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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,654	12/16/2004	Christopher S. Brook	P51365	6840

20462 7590 08/02/2006

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EXAMINER	
FREISTEIN, ANDREW B	
ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/518,654	BROOK ET AL.	
	Examiner	Art Unit	
	Andrew B. Freistein	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *6-19 and 21-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/16/04; 05/05/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are currently pending.

Priority

This application is a 371 of PCT/US03/20408, filed 06/27/2003, which claims benefit of US Provisional Application No. 60/392,175, filed 06/27/2002.

Information Disclosure Statement

Applicant's information disclosure statements (IDS), filed on 05/05/2006 and 12/16/2004, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Restriction Requirement

In a response filed 07/07/2006, Applicant elected (with traverse) **Group I, claims 1-5 and 20**.

Applicant traverses the restriction requirement first asserting that the referenced US patent 4,053,067 is not related to carvedilol salts. Examiner agrees with Applicant, because this was a typographical error. Examiner intended to cite Wiedemann et al., US Provisional Application No. 4,503,067, which is cited in the instant specification as evidence of the existence of carvedilol.

Although Examiner mistakenly cited the wrong reference, the concept is the same. Unity of invention is lacking in the instant application, because the technical feature that is common among the claims fails to make a contribution over the prior art. In the instant case, the technical feature is carvedilol, which is a known product and thus is not a "special" technical feature that defines a contribution over the prior art.

Applicant further traverses the restriction requirement, because there is no search burden. Examiner did not allege in the previous Office Action that a search burden exists, but rather a "serious burden" exists as a result of the lack of unity of invention (see p. 5).

Therefore, the restriction requirement is maintained and made final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedemann et al., US 4,503,067 and Hildesheim et al., US 7,056,942.

Claim 1 is drawn to "A compound which is carvedilol dihydrogen phosphate hemihydrate." Claims 2-5 are dependent claims drawn to carvedilol dihydrogen phosphate hemihydrate, which show specific characteristics such as an x-ray fraction pattern, an infrared spectrum and a Raman spectrum. Claim 20 is drawn to a

pharmaceutical composition comprising the compound carvedilol dihydrogen phosphate hemihydrate.

Determining the Scope and Content of the Prior Art

Wiedemann et al. disclose and claim the compound of carvedilol and the salts thereof with physiologically acceptable acids (col. 15, line 28-65; see also the instant Specification, p. 1, lines 24-25).

Hildesheim et al. disclose that the term "carvedilol" includes hydrates and solvates of carvedilol and the hydrate and solvate forms are only distinct from one another in their powder X-ray diffraction patterns and their thermal profiles (see US 7,056,942, col.4, lines 66-67 and col. 5, lines 23-25).

Ascertaining the Difference Between the Prior Art and the Instant Application

Wiedemann et al. disclose carvedilol and the salts thereof. However, the instant application specifically claims "carvedilol dihydrogen phosphate hemihydrate", which is a specific salt of carvedilol.

Hildesheim et al. disclose polymorphs of carvedilol.

Finding Prima Facie Obviousness

Changing the form, purity, color, or other characteristic of an old product without a new use as a result thereof does not render product patentable where utility remains the same. *Ex parte Hartop*, 139 USPQ 525. Absent a showing of a viable unexpected, unobvious and superior properties, the instant claimed compound would have been suggested to one skilled in the art.

Further, changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art. *In re Cofer*, 148 USPQ 268 (CCPA 1966). Therefore, absent a showing of unobvious and superior properties, the instant claimed salt form of the known compounds would have been suggested to one skilled in the art. Additionally, since Applicant(s) are claiming a similar method of using the salt forms to that of the original compound (the treatment of hypertension), a showing of unobvious and superior properties in using this particular salt form for this similar method of use would also have to shown.

One skilled in the art would have been motivated to prepare different salt forms of known pharmaceutically useful compounds with the expectation of obtaining a pharmaceutically useful benefit, such as longer shelf life, stability, enhanced deliverability, etc. Therefore, absent a showing of unobvious and superior properties, the instant claimed crystalline forms of known compounds would have been suggested to one skilled in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 34 of copending Application No. 10/977,230. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claim 1 is drawn to "A compound which is carvedilol dihydrogen phosphate hemihydrate." Claim 20 is drawn to a pharmaceutical composition comprising the compound carvedilol dihydrogen phosphate hemihydrate.

Determining the Scope and Content of the Prior Art

Claim 2 of the copending application is drawn to a crystalline salt, anhydrous form or solvate of carvedilol selected from the group consisting of: carvedilol hydrogen phosphate, carvedilol dihydrogen phosphate, carvedilol dihydrogen phosphate hemihydrate, carvedilol dihydrogen phosphate dihydrate, carvedilol dihydrogen phosphate methanol solvate, carvedilol hydrobromide monohydrate, carvedilol hydrobromide dioxane solvate, carvedilol hydrobromide 1-pentanol solvate, carvedilol hydrobromide 2-methyl-1-propanol solvate, carvedilol hydrobromide trifluoroethanol solvate, carvedilol hydrobromide 2-propanol solvate, carvedilol hydrobromide n-propanol solvate #1, carvedilol hydrobromide n-propanol solvate #2, carvedilol hydrobromide anhydrous forms or anhydrous, carvedilol hydrobromide ethanol solvate, carvedilol hydrobromide dioxane solvate, carvedilol monocitrate monohydrate, carvedilol mandelate, carvedilol lactate salt, carvedilol maleate, carvedilol sulfate, carvedilol glutarate, and corresponding anhydrous, solvates thereof.

Claim 34 is drawn to a pharmaceutical composition comprising a compound of claim 2 and a pharmaceutically acceptable adjuvant, carrier diluent, and/or excipient.

Ascertaining the Differences Between the Copending Application and the Instant Application

The copending application is drawn to a crystalline salt, anhydrous form or solvate of carvedilol, which can be 22 different products. Claims 1-5 and 20 the instant application is drawn to the single compound of carvedilol dihydrogen phosphate hemihydrate, although the instant application is drawn to 4 additional carvedilol compounds that are non-elected subject matter.

Finding Prima Facie Obviousness

One of ordinary skill in the art would be motivated to produce the compound and pharmaceutical composition of the instant application with the disclosure of the copending application. The instant compound carvedilol dihydrogen phosphate hemihydrate is the first example in the copending application and is a preferred embodiment (see p. 17, ex. 1; p. 24, lines 26-32; p. 29, Ex. 1). Further, there is x-ray powder diffractogram data, FT-Ramam spectrum data, and FT-IR spectrum data for the compound carvedilol dihydrogen phosphate hemihydrate of the instant application (p. 4-5). Thus, one of ordinary skill in the art would be motivated to produce the compound of the instant application with the disclosure of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to "A compound which is carvedilol dihydrogen phosphate hemihydrate." Claims 2-5 are dependent claims drawn to carvedilol dihydrogen phosphate hemihydrate, which show specific characteristics such as an x-ray fraction pattern, an infrared spectrum and a Raman spectrum. Claim 20 is drawn to a pharmaceutical composition comprising the compound carvedilol dihydrogen phosphate hemihydrate.

The preliminary amendment filed 12/16/2004 deletes the term "crystalline" from claim 1. This is new matter. Example 1 of the instant specification identifies a crystalline form of carvedilol dihydrogen phosphate hemihydrate as Form I. Similarly, the provisional application 60/392,175 identifies a crystalline Form I as example 1. Thus, the deletion of "crystalline" from claim 1 in the preliminary amendment is an attempt to broaden the scope of the claim from a crystalline form to include all forms of the compound carvedilol dihydrogen phosphate hemihydrate.

According to MPEP 608.04(b), the preliminary amendment must be described in Oath/Declaration and in this case the preliminary amendment is not mentioned. In order to overcome this rejection, applicant must submit (1) a new oath or declaration that refers to the preliminary amendment or (2) file an amendment that reinserts "crystalline" in claim 1.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

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Joseph K. McKane
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Date: July 28, 2006